UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
AIR ENFORCEMENT SECTION, REGION III
WHEELING OFFICE
1060 Chapline Street, Suite 303
Wheeling, West Virginia 26003

October 17, 2002

MEMORANDUM

SUBJECT: Air Compliance Inspection Report

FROM: Richard W. Eaton (3AP12) RWE
Env. Protection Specialist, Wheeling Office

TO: Christopher B. Pilla (3AP12)
Chief, Air Enforcement Branch

Attached is a copy of the Air Compliance Inspection report on B. Braun Medical , Inc. for your review. If you have any questions, please call (304) 234-0265.

Attachments: (1) Initial Notification

(2) Performance Test

(3) Ethylene Oxide Usage Report

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AIR COMPLIANCE INSPECTION REPORT

I. General Information:

Company Name: B. Braun Medical, Inc.

Address: 901 Marcon Blvd.

(City): Allentown (County): Lehigh (State): PA

Phone Number: (610) 266-0500 Fax Number: (610) 266- 6294

Form of Ownership: Private AFS#: 42 077 00181

Date(s) of Inspection: August 27, 2002

Arrival Time: 8:30am Departure Time: 12:30pm

Company Representatives: Steve Stancik, Sterilization Manager

Thomas McIntosh, Compliance Manager

State Representatives: Sue Bolstrum, Pennsylvania Dep't of Environmental Protection, Bethlehem District Office

EPA Representatives: Richard W. Eaton, APD- Wheeling Office

II. Type of Facility:

B. Braun Medical, Inc. is a manufacturer of sterile, disposable class I and class II medical devices such as catheters and valves. The Allentown, Pennsylvania facility is one of four B. Braun manufacturing plants in the United States. The parent company is located in Berlin, Germany and is privately owned. The Allentown plant was built and opened in 1985 and employs over 1,000 people.

III. Specific Information:

B. Braun Medical operates eight sterilization chambers for sterilizing the medical instruments manufactured at the Allentown plant. The sterilization chambers have the following capacities:

Chamber #	Capacity
#1	1,000 cu. ft.
#2	1,000 cu. ft.
#3	1,000 cu. ft.
#4	1,000 cu. ft.
#5	1,250 cu. ft.
#6	1,250 cu. ft.
#7	3,600 cu. ft.
#8	130 cu. ft.

Medical products to be sterilized are preconditioned with steam and then loaded into one of the eight sterilization chambers. The air inside the chamber is evacuated using a vacuum pump to decrease the chamber pressure. Steam, nitrogen, ethylene oxide, and again nitrogen are introduced into the chamber. When sterilization is complete, the chamber is flushed with nitrogen and the effluent is drawn by a vacuum pump to a Chemrox Deoxx Acid Scrubber system. The scrubber exhausts through a 21 foot stack on top of the manufacturing facility. The Deoxx scrubber unit removes the ethylene oxide and converts it to ethylene glycol by hydrolysis.

An initial notification was submitted by B. Braun Medical, Inc. on May 6, 1996 as required by the Ethylene Oxide Sterilizer NESHAP. The facility uses over ten tons of ethylene oxide per year. The company provided records pertaining to ethylene oxide usage for the previous twelve month period.

A performance test was run on the scrubber on October 26, 1996 to test the efficiency of the Deoxx scrubber system. The efficiency of the three test runs was over 99% and the company monitors the scrubber liquor level once per week. The company provided examples of the weekly monitoring reports which are attached to the report.

B. Braun Medical uses an aeration room to complete off-gassing of the sterilized products. The aeration room vent is controlled by a Donaldson Catalytic Oxidizer. A continuous monitor is used to record the bed temperature on the catalytic oxidizer. The monitor records the bed outlet temperature which was recording a temperature of about 300° F. The filters are checked approximately every three months and the filters are normally changed on a yearly basis. The company indicated that this unit will be tested again possibly within the next twelve months.

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October 17, 2002

MEMORANDUM

SUBJECT: Compliance and Recommendations for B. Braun Medical, Inc.

FROM: Richard W. Eaton (3AP12) RWE
Env. Protection Specialist, Wheeling Office

TO: Christopher B. Pilla (3AP12)
Chief, Air Enforcement Branch

1. The B. Braun Medical, Inc. facility in Allentown, Pa. was in compliance with the Ethylene Oxide Commercial Sterilization NESHAP regulations in 40 CFR, Part 63, Subpart O.

2. A copy of a future performance test has been requested for this facility.

Attachment #1
August 05/11/96 AWH

Date: May 6, 1996

Example 2 Initial Notification Report

Applicable rule: Subpart O--National Emission Standards for EO Commercial Sterilization and Fumigation Operations

Effective date:[1] December 8, 1994

All facilities using 1 ton or more of ethylene oxide (EO) per year are required to submit this notification. See section 63.366 of subpart O and section 63.9 of subpart A.

The initial notification should be submitted to the appropriate authority within 120 days after the effective date (120 days after the effective date is April 8, 1995) or within 120 days after initial startup, whichever is later.

1. Print or type the following for each plant in which EO commercial sterilization and fumigation operations are performed:

Name of Owner/Operator B. Braun Medical , Inc.

Mailing Address 824 12th Avenue

City Bethlehem State PA Zip Code 18018

Plant Name B. Braun medical ,Inc.

Plant Address (if different than owner/operator's)

Street Address 901 Postal Road

City Allentown State PA Zip Code 18103

Phone Number (610) 266-0500

Plant Contact/Title Steve Stancick, Sterilization Manager

The only EO commercial sterilization and fumigation operations that are exempt from subpart O are those used for research and laboratory purposes (see section 112(c)(7) of the Clean Air Act).

2. Note the initial startup date for the source: May 17, 1987
Month/day/yr

[1]The date of promulgation in the Federal Register.

Plant Name: B. Braun Medical, Inc.

3. Check the boxes that apply; note the **compliance date.**[2]

		Compliance Date
☒	Initial startup occurred on or before December 8, 1997.	December 8, 1997
☐	Initial startup occurred after December 8, 1997.	_____ (compliance date = initial startup date)

☒ The facility uses 10 tons of EO or more per year.

☐ The facility uses 1 to 10 tons of EO per year.

4. Complete the following table for each vent type (i.e., sterilization chamber or aeration room). If additional space is needed, make copies of this page. The first row of each section gives examples of appropriate entries.

Vent type	Sterilization chamber size (m^3)	No. of chambers of this size
Sterilization chambers	Example - 30 m^3	2
	29m^3	4
	36m^3	2
	4m^3	1
	7m^3	1
CUMULATIVE STERILIZATION CHAMBER SIZE (m^3): [a] 199m^3		

Vent type	Aeration room or aeration chamber size (m^3)	No. of rooms or chambers of this size
Aeration rooms or aeration chambers	Example - 280 m^3	1
	366m^3	1

[a]Summation of the volume of all sterilization chambers at the facility.

[2]The date a source is required to be in compliance with the Ethylene Oxide Commercial Sterilization and Fumigation NESHAP.

Plant Name: B. Braun Medical, Inc.

8. Print or type the name and title of the Responsible Official for the plant:

Thomas R. Ronca — Senior Vice Presidentof Research & Development

Name — Title

A Responsible Official can be:

- The president, vice-president, secretary, or treasurer of the company that owns the plant;
- The owner of the plant;
- The plant engineer or supervisor; or
- A government official if the plant is owned by the Federal, State, City, or County government.

The Responsible Official must certify below that all of the information presented in this initial report is accurate and true.

I certify the information contained in this report to be accurate and true to the best of my knowledge.

5/10/96

Signature of Responsible Official — Date

Plant Name: B. Braun Medical, Inc.

5. Complete the following table. If additional space is needed, make copies of this page. The first three rows give examples of appropriate entries.

Vent type (e.g., SCV, ARV, CEV)[a]	Applicable emission limitation[b]
Example - two SCV (30 m^3)	99% emission reduction
Example - one ARV (280 m^3)	99% emission reduction
Example - two CEV (30 m^3)	5,300 ppmv
4 SCV (29m^3) 2 SCV (36m^3) 1 SCV (4m^3)	99% emission reduction 99% emission reduction 99% Emission reduction
1 SCV (7m^3) 1 ARV (366m^3) 4 CEV (29m^3)	99% emission reduction 99% emission reduction 5,300 ppmv
2 CEV (36m^3) 1 CEV (4m^3) 1 CEV (7m^3)	5,300 ppmv 5,300 ppmv 5,300 ppmv

[a]SCV = sterilization chamber vent (includes sterilization chamber vacuum pump); ARV = aeration room vent; CEV = chamber exhaust vent (also referred to as back draft or door hood vent).
[b]Emission limitations could be: 99% emission reduction; 1 ppmv concentration limit or 99% emissions reduction; or 5,300 ppmv concentration limit.

6. Emissions from the sterilization chamber vacuum pump will be controlled as follows (check one):

☒ Emissions will be vented to a control device (i.e., control device for the sterilization chamber vent) and will be reduced by 99 percent.

☐ A recirculating-fluid vacuum pump will be used.

7. Attach additional pages including any other information required by the State or local agency.

Attachment #2

3.0 TEST PROCEDURE

The procedure used was as outlined in the included document labeled SOP #11, Rev.#:New). The location of the stack sampling was approximately half way between the Deoxx Unit and the roof line. The entire length encompasses about 15' of 6" PVC pipe. Since the sample line was located within the building, the use of a heat traced line was not necessary. Vacuum pump rate monitoring was done prior to the test program, the results are shown in the included graph. Due to the explosive nature of the gas, it was recommended by the manufacturer to obtain the rate curve of the vacuum pump prior to the test program.

For the purpose of this testing, only the first post evacuation was sampled. It was felt that this would represent the worst case scenario due to the largest quantities of ethylene oxide being pushed through the system. Additional testwork would only increase the efficiency numbers.

Two test runs will be performed, one on chamber #6 and one on chamber #3. These two chambers represent the fastest and slowest pumps currently in operation. % efficiency should be directly proportional to flow velocity.

4.0 TEST RESULTS

The test work has shown that efficiencies of 99+% can be obtained by the Deoxx unit. The actual results are as follows:

DATE	STER. #	% EFF.	EtO (in) (lbs)	ETO (out) (lbs.)	STER. VOL.(Ft^3)
10-25-95	6	99.2	53.5	0.44	1250
10-26-95	3	99.4	42.3	0.24	1050

Attachment #3

ARC Speciality Products - EtO

2001- 2002

Cost/lb = $2.09

Date Delivered	Bill Number	Cost	# Drums	Gross Wt.	Net Wt.	Drums Returned
08/07/01	51506	$5,071	6	3,989	2,400	9
08/14/01	51641	$10,142	12	7,948	4,800	10
08/21/01	51759	$10,142	12	7,971	4,800	15
08/28/01	51900	$10,142	12	7,960	4,800	10
09/04/01	52019	$9,297	11	7,335	4,400	6
09/11/01	52169	$6,762	8	5,302	3,200	13
09/18/01	52272	$14,368	17	11,286	6,800	12
09/25/01	52429	$7,607	9	5,968	3,600	12
10/02/01	53558	$10,142	12	7,960	4,800	12
10/10/01	52728	$9,297	11	7,283	4,400	13
10/16/01	52832	$10,988	13	8,613	5,200	14
10/23/01	52979	$11,833	14	9,302	5,600	11
10/30/01	57255	$10,142	12	7,965	4,800	12
11/06/01	152	$9,297	11	7,322	4,400	12
11/13/01	316	$10,142	12	7,970	4,800	11
11/20/01	506	$10,988	13	8,640	5,200	14
11/27/01	591	$5,071	6	3,979	2,400	4
12/04/01	776	$10,142	12	7,924	4,800	13
12/11/01	895	$6,761	8	5,317	3,200	11
12/18/01	1086	$10,988	13	8,646	5,200	9
12/26/01	1237	$10,142	12	7,966	4,800	12
1/2/2002	1321	$5,852	7	4,629	2,800	7
1/8/2002	1446	$6,688	8	3,200	5,300	10
1/15/02	1621	$7,524	9	6,005	3,600	9
1/22/02	1775	$7,524	9	5,985	3,600	11
1/29/02	1918	$10,868	13	8,585	5,200	15
2/5/02	2109	$12,540	15	9,948	6,000	13
2/12/02	2266	$10,032	12	7,964	4,800	12
2/19/02	2400	$12,540	15	10,125	6,000	13
2/26/02	2577	$6,688	8	5,328	3,200	8
3/5/02	2750	$10,868	13	8,628	5,200	12
3/12/02	2927	$11,704	14	9,299	5,600	12
3/19/02	3050	$9,196	11	7,331	4,400	10
3/26/02	3222	$10,032	12	7,947	4,800	12
4/2/02	3363	$8,360	10	6,682	4,000	11
4/9/02	3536	$8,360	10	6,674	4,000	12
4/16/02	3709	$10,032	12	7,974	4,800	10
4/23/02	3870	$8,360	10	6,750	4,000	11
4/30/02	4016	$8,360	10	6,622	4,000	11
5/7/02	4169	$10,032	12	7,967	4,800	12
5/14/02	4335	$10,032	12	7,970	4,800	11
5/21/02	4476	$11,704	14	9,347	5,600	12
5/28/02	4630	$8,360	10	6,750	4,000	10
6/4/02	4755	$6,688	8	5,327	3,200	12
6/11/02	4927	$10,868	13	8,642	5,200	11
6/18/02	5054	$9,196	11	7,283	4,400	13
6/25/02	5243	$10,868	13	8,640	5,200	11
7/2/02	5386	$10,032	12	8,019	4,800	13
7/9/02	5487	$6,688	8	5,410	3,200	5
7/16/02	5650	$6,688	8	5,302	3,200	11
7/23/02	5822	$10,868	13	8,638	5,200	10
7/30/02	5987	$8,360	10	6,688	4,000	9
8/6/02	6179	$8,360	10	6,715	4,000	11
8/12/02	6307	$8,360	10	6,664	4,000	11
8/20/02	6431	$8,360	10	6,648	4,000	9
SUM 8/7/01 thru 8/6/02		**$485,376**	**578.0**	**382,305**	**233,300**	**574.0**
AVG. per MONTH		**$40,448**	**48.2**	**31,859**	**19,442**	**47.8**
AVG. per WEEK		$9,334	11.1	7,352	4,487	11.0